

crispprd 1.0



Abstract

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Project Title: PSYCHOIMMUNE OUTCOMES: INTERVENTION IN BREAST CANCER

Abstract: *The specific aims of this study are (1) to examine immunological, psychosocial, and clinical symptom outcomes of an 8-week integrated support program for patients with newly diagnosed breast cancer, and (2) to determine whether the support program has differential effects on patients with persistently low versus high baseline natural killer cell (NK) activity pattern (below versus above median NK activity x 2). The integrated support program includes weekly stress management and social support programs and exercise training activities three times a week. Background and Significance: Cancer diagnosis and treatment are a major source of significant psychological, emotional, and physical distress. Most previous interventions have been limited by a unidimensional approach (psychosocial or physical support, not both), and by the lack of immunological assessments. Given the importance of mind-body interactions in human functioning, an integrated approach of concurrent psychological and physical support will be most beneficial to assist patients in distress. Further, there is indication that breast cancer patients with lower baseline NK activity pattern have a poorer prognosis than those with higher baseline NK activity pattern. A comprehensive examination of an integrated approach will provide insights to improving quality of life for patients with newly diagnosed breast cancer. Design and Method: Using a longitudinal, experimental design with pretest and posttest, 90 patients with stage I-IV newly diagnosed breast cancer will be stratified by disease stage (I-IIB vs. locally advanced) and randomly assigned to the Experimental (intervention) or Control (wait-list) group. NK activity will be examined twice prior to the beginning of intervention to determine the pattern of NK activity. The intervention will begin at the start of chemo- or radiotherapy. Post-intervention data will*

be collected immediately after intervention and at 6 and 12 months from the initiation of intervention, coinciding with patients' routine clinic visits. Dependent Measures and Analysis: The impact of intervention will be measured on immune responses (NK activity and number, lymphokine activated killer cell activity, IL-1alpha, IL-2 and interferon-gamma), psychosocial well-being (distress, mood states, and quality of life), and clinical symptoms (fatigue, nausea, vomiting, and sleep). Longitudinal data analysis methods will be employed to analyze repeated measures of outcome variables, whereas 2-sample t-test or nonparametric Wilcoxon rank-sum test will be used to perform univariate analysis.

Thesaurus Terms:

breast neoplasm, human therapy evaluation, natural killer cell, neoplasm /cancer therapy, outcomes research, psychological aspect of cancer, psychoneuroimmunology behavior therapy, interferon gamma, interleukin 1, interleukin 2, longitudinal human study, neoplasm /cancer classification /staging, neoplasm /cancer immunology, neoplasm /cancer relapse /recurrence, psychological stressor, social support network, stress management behavioral /social science research tag, clinical research, female, human subject, women's health

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